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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040223

Application Number: 09/729,498
Filing Date: December 04, 2000
Appellant(s): KIRCHER ET AL.

Roger D. Greer
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 12, 2003..

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief was correct. However, the examiner has dropped the rejection of claims 6-8, 12-13, 19-21, 23, and 28-29. A correct statement of the status of the claims is as follows:

Claims 6-8, 12-13, 19-21, 23, and 28-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-4, 10, 24-27 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

The rejection of claims 5-23 and 28, 30-31 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief was correct. However, the examiner has dropped the rejection of claims 6-8, 12-13, 19-21, 23, and 28-29.

(9) Prior Art of Record

5,228,485	LEWIS et al.	7-1993

Baxter "Multitask Operating System for Automix Compounders Version 2.30" May 1999

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

1. Claims 1-4, 10, and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis et al. US 5,228,485 (see column 2 lines 29-32; column 5, lines 40-53; column 6, lines 44-64; column 9, lines 4-36; Drain Routine section).

Lewis et al. discloses an invention that generally relates to systems for transferring fluids from individual source containers to a receiving container, and more

specifically relates to systems for transferring liquid drugs from individual vials, bottles, or bags to a single solution bag or bottle for administration to a patient.

In hospitals, it is frequently necessary to provide solutions for intravenous administration to a patient which contain a variety of drugs in a single solution container. A common example of such a need arises when a patient is receiving all of his nutritional needs intravenously. In this situation, the patient will typically receive a basic solution containing amino acids, dextrose, and fat emulsions which provide a major portion of the patient's nutritional needs (prescriptions). However, this solution is insufficient to maintain a patient for an extended period of time. Therefore, a typical total parenteral solution includes as many as eight to twelve additional additives. The additives are typically minute quantities of vitamins, minerals, electrolytes, etc. Therefore, when a pharmacist is preparing a solution for total parenteral nutrition, it is necessary for the pharmacist to individually add each of the additional additives to a solution container after the base solutions have been added. This is typically done with individual syringes and requires a relatively long time on the part of a pharmacist to accurately add all additives to each of the required additives.

An object of the invention is to provide a means for periodically flushing the measuring chamber described above to rinse the chamber of any incompatible drugs. In accordance with the invention, a device 10 (FIG. 1) is provided for accurately transferring individual doses of separate fluids from individual source containers 12. Each individual source container may contain a different fluid 14. In some cases, the fluid in one container may be incompatible with fluids contained in other source

containers. According to the invention, fluid is transferred from each source container 12 through a separate individual fluid conduit 16 to a single chamber 18. The chamber 18 is suspended from a load cell assembly 20. The load cell 20 constantly weighs the total weight of the chamber to develop an output signal which is indicative of the amount of fluid in the chamber 18 at any given time.

The device comprises a control means that may allow a second fluid to flow into the chamber when a first fluid is still present in the chamber if the first and second fluids are compatible with each other and there is sufficient empty space remaining in the chamber to receive the entire amount of the second fluid to be dispensed. The control means will not allow a second fluid to enter the chamber when a first fluid is still present if the two fluids are incompatible with each other, when properly programmed, or if insufficient room exists in the chamber (which inherently implies that the device may be programmed to compare pharmaceutical components relative to one another allowing the order of dispensing to be determined; general rules of order of admixing).

After a transfer set has been installed in the device, the operator is then ready to program the device to indicate the amount and type of each fluid to be transferred from each of the individual source containers into the receiving container. Information can be input into the device from one of two sources. One source of entering information into the device is a keyboard entry device, illustrated in FIG. 22.

When the device is turned on, a system of internal checks is automatically performed by the control means 32. In the preferred embodiment of the invention, two microprocessors are used in the control means 32. While a variety of microprocessors

can be used, in one embodiment of the invention, an Intel 8031 microprocessor can be used for both of the microprocessors. One microprocessor serves as a master microprocessor and another microprocessor serves as a pumping control microprocessor. A simplified block diagram of a typical microprocessor is illustrated in FIG. 23. As can be seen in this figure, a typical microprocessor includes an internal random access memory 222 and a plurality of in/out (I/0) ports 224. The microprocessors include a variety of hardware registers which can be programmed to perform special functions. In the preferred embodiments of the subject invention, the special function hardware registers 226 may include serial interface registers 228, timer/counters 230, and a stack pointer 232. Each of these aspects of the microprocessor as used in the preferred embodiment of the subject invention will be discussed in greater detail below. In addition to the internal features of a typical microprocessor as briefly described above, additional external hardware is present in a typical microprocessor control device. For example, an external RAM 234, external in/out ports 236(LAN connection), and a programmable memory (ROM) 238 are required to allow a microprocessor to perform the desired functions in accordance with the invention.

FIG. 26 illustrates a display panel for displaying volumetric and specific gravity information for each source container. The display panel displays the specific gravity as programmed by an operator for a particular source container as illustrated by LCD display panel 250. The volume of fluid to be transferred from a specific source container to the receiving container as programmed by an operator is illustrated by another LCD

display panel 252. Each individual source container has separate LCD display panels 250 and 252 for displaying the specific gravity and volumetric information for each source container.

The programmer may either enter the volume or the specific gravity of the fluid to be transferred. Typically, during initial set up of the device, the specific gravity for each source container will be initially programmed by the operator.

If the pump control microprocessor is ready to receive data, the master microprocessor computes (conversion) the weight of fluid to be transferred from each individual source container to the receiving container given the volume and specific gravity information input in the device during the keyboard entry mode. This computation is essentially identical to the computations described in U.S. Pat. No. 4,513,796 entitled "High Speed Bulk Compounder" issued Apr. 30, 1985. This application is incorporated herein by reference. The pump control routine checks to see if any of the information entered by the operator is out of a predetermined range. For instance, in the preferred embodiment of the invention, the allowable range for specific gravity is between approximately 0.5 and 3.0. The minimum volume to be transferred has to be, for example, at least one milliliter in the preferred embodiment of the invention. If any of the information is determined to be outside of these ranges, the pump control routine notifies (alarms) the operator by causing the display 250 or 252 (FIG. 26) which is out of range to flash. This is illustrated by block 302 in FIG. 28.

The drain routine is simply a series of checks to determine if the chamber needs to be drained. The first check performed by the drain routine is to determine if the last

source container has been pumped. This check is illustrated by decision diamond 506 in FIG. 36. If the last source container has not been pumped, the drain routine next checks to see if a rinse is to follow the source container that was just pumped. This check is illustrated by decision diamond 508. Normally, a rinse will not be conducted unless the next fluid to be pumped is incompatible with the previous fluid, or if the previous fluid pumped was the last fluid to be pumped. The next check performed by the drain chamber routine is to determine if the next source container to be pumped is supposed to be followed by a rinse. This is illustrated by decision diamond 510. In the preferred embodiment of the invention, if the next source container is to be followed by a rinse, then a drain operation will occur prior to filling the chamber with that fluid.

Claim Rejections - 35 USC § 103

2. Claims 5, 9, 11, 14-18, 22, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. as applied to claims 1-4, 10, and 24-27 above, and further in view of *Multitask Operating System for Automix® Compounders Version 2.30*; Baxter May 1999.

Lewis et al. does not specifically recite that the pharmaceutical components comprises groups consisting of lipids and sterile water.

Baxter discloses a method of operating or programming an apparatus for compounding in which the patient and prescription data, performance of compounding calculations, printing reports, and support of the nutritional solution is detailed.

Three levels of user passwords including Administrator, Pharmacist, and Technician manage access to the programs of the device. The device also requires

that patient's profile be entered when creating a prescription. The profile includes such information as the patient's weight, age, name, as well as the patient type (adult, pediatric, neonate, etc.) (see 2-5). As seen on the display of page 2-16 one of the components may be **sterile water and Lipids** as given on page 2-19. Before the prescription of a patient is compounded and verified via password, a series of validity tests are performed to warn the user producing warnings for overfill, electrolyte, osmolarity, ingredient volume, patient weight, and calcium phosphate solubility (pages 2-24 – 2-26). As seen on pages 3-4 and 3-5 the phosphate additive is added before the calcium additive. The device is also capable of maintaining history logs of the patients information.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that lipids and sterile water may be components of the pharmaceutical components for Baxter discloses that these are common components used in the development of nutritional needs for adult, neonatal, and pediatric patients.

(11) Response to Argument

Issue I

Appellant asserts the examiner's rejection of claim 1 on the basis of the Lewis et al. U.S. Patent N0.5,228,485 (hereinafter 'Lewis") is improper because it grossly exaggerates the Lewis reference far beyond what is justified. Appellant further asserts neither Lewis nor the Baxter reference used in the 103 rejections of other claims, anticipate, teach or suggest several features of the claims, including the two independent claims 1 and 24.

Appellant further states, "Appellant's are well aware of the content of this prior art because the Lewis patent is assigned to Clintec Nutrition Co., which is related to the assignee of the present invention and the Baxter reference is an operating manual of one of the assignee's own products that is also referred to in the present application."

Appellant's relationship to the assignees of the prior art applied in the instant application are irrelevant, for the prior art has been applied under the statutory basis of 35 U.S.C. 102(b).

In appellant's appeal brief, page 8, second paragraph, appellant states "During the prosecution of this application the examiner had underlined the word "incompatible" several times during the characterization of the Lewis reference as if the knowledge that some drugs are not compatible with one another, in and of itself, is significant to the present invention. **It simply is not**."

The examiner asserts that appellant's implication that the functionality of the device as related to determining the compatibility/incompatibility of components is not a significant feature of the device is contradictive. During the prosecution of the case as well as in the filed appeal brief (see, page 9), appellant has relied on arguments directed to the device of the instant application ability function as to determine the compatibility of the components as basis for patentability over the prior art.

It is not clear how appellant asserts that in one instance the compatibility function (as stated above) is insignificant but is yet recited in the claims and relied upon in appellant's arguments as a means of distinction.

Appellant's arguments are directed to the capability of the computing means to store data, determine the compatibility of pharmaceutical components, and determine the order in which the components are mixed. Appellant argues that Lewis et al. US 5,228,485, teaches a device in which an operator is required to program the device in order for it to perform the above functions.

The examiner asserts that all computers or automated devices must be programmed at some point in order for it to function. Therefore, appellant's device must be equipped with a table or data which has been entered or collected by an operator at some point and time. It is understood that technology does exist which allows a computer to "learn" after its been initially programmed to function or run specific routines.

It appears that the issue of the patentability of the instant invention and that of Lewis may be the ability of the computer or control means to "learn" or time at which the operator inputs data (neither of which is encompassed by the breathe of the claim).

In column 6, lines 44-53 of Lewis et al. teaches:

"The **control means** may allow a second fluid to flow into the chamber when a first fluid is still present in the chamber **if the first and second fluids are compatible** with each other and there is sufficient empty space remaining in the chamber to receive the entire amount of the second fluid to be dispensed. **The control means will not allow a second fluid to enter the chamber when a first fluid is still present if the two fluids**

are incompatible with each other, when properly programmed, or if insufficient room exists in the chamber. The control means 32 enhances fluid flow from the chamber 18 into the receiving container 24 by causing the pressure means to generate a positive pressure in pressure conduit 26 which is in fluid communication with the chamber 18. This causes a positive pressure in the chamber so that when the second occlusion means 30 is opened to allow fluid to flow from the chamber to the receiving container 24, the positive pressure will force the fluid out of the chamber and into the receiving container 24. This greatly reduces fluid retention in the chamber 18."

As recited above, the control means does have the ability of determining if the components are compatible and altering the order of dispensing when properly programmed.

The issue of the device being programmed by an operator has no patentable weight on the claimed material for as recited herein above and below the control means does determine the compatibility of the components and whether or not a fluid is dispensed (order of dispensing).

As to claim 2 and 3, the ability of a computer to mathematical calculations such as conversions are inherent features that are commonly used to relay data to other electrical components as well as present results in a consistent format such as the metric system.

As to claim 4, the issue of compatibility has been addressed above.

As to claims 5, 9, 13, 30 and 31, it is clearly disclosed by Baxter as seen on the display of page 2-16 one of the components may be **sterile water and Lipids** as given on page 2-19. It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that the device of Lewis could be modified to identify components such as water and Lipids and there compatibility with other components included in the system.

Issue II

Appellant asserts "Lewis nor Baxter even remotely teach or suggest the computing means determining the order in which components are transferred so that the order is in accordance with a set of general rules of order of admixing as specified in this claim.

The examiner respectfully disagrees for Lewis discloses: The device comprises a control means that may allow a second fluid to flow into the chamber when a first fluid is still present in the chamber if the first and second fluids are compatible with each other and there is sufficient empty space remaining in the chamber to receive the entire amount of the second fluid to be dispensed. The control means will not allow a second fluid to enter the chamber when a first fluid is still present if the two fluids are incompatible with each other, when properly programmed, or if insufficient room exists in the chamber (which inherently implies that the device may be programmed to compare pharmaceutical components relative to one another allowing the order of dispensing to be determined; general rules of order of admixing).

As to the rinsing determination of the system Lewis discloses a system for determining the required rinsing as stated the in the passage: The drain routine is simply a series of checks to determine if the chamber needs to be drained. The first check performed by the drain routine is to determine if the last source container has been pumped. This check is illustrated by decision diamond 506 in FIG. 36. If the last source container has not been pumped, the drain routine next checks to see if a rinse is to follow the source container that was just pumped. This check is illustrated by decision diamond 508. Normally, a rinse will not be conducted unless the next fluid to be pumped is incompatible with the previous fluid, or if the previous fluid pumped was the last fluid to be pumped. The next check performed by the drain chamber routine is to determine if the next source container to be pumped is supposed to be followed by a rinse. This is illustrated by decision diamond 510. In the preferred embodiment of the invention, if the next source container is to be followed by a rinse, then a drain operation will occur prior to filling the chamber with that fluid.

As to claims retrieval of data related to a patient profile as addressed in claims 15-18, Baxter discloses also requires that a device that requires the patient's profile be entered when creating a prescription. The profile includes such information as the patient's weight, age, name, as well as the patient type (adult, pediatric, neonate, etc.) (see 2-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that the information as related to a patient is pertinent in determining the type of prescription suitable for a specific patient. Further more it would have been obvious at the time of the invention to modify the device of Lewis to be

programmed to determine the compatibility of a component with that of the pertinent information of that of a patient.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Brian Gordon
March 2, 2004

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